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10/039,977	01/08/2002	Peter Nash	C150.12.3E	8750
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Richard O. Bartz Suite 350 6750 France Avenue South Edina, MN 55435			HUYNH, PHUONG N	
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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/039,977	<b>Applicant(s)</b> NASH ET AL.	
	<b>Examiner</b> Phuong Huynh	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 January 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

### DETAILED ACTION

1. Claims 1-18 are pending and are being acted upon in this Office Action.
2. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
3. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of a method as set forth in claims 1-18. The instant claims are drawn to a method of reducing or eliminating the incidence of illnesses caused by a wide range of colony-forming illness-causing "immunogens" that adhere to the rumen or intestinal tracts of *any* food animals and the method of making antibody to said undisclosed colony-forming illness-causing immunogens, such as any serotypes of *E coli*, *Listeria*, *Salonella* and *Campylobacter* bacteria recited in claim 2 and encompassed by claim 1.

The specification discloses only a method of promoting the growth of the food animal by inoculating female bird with the specific immunogen such as P antigen from *P. anaerobius*, CS antigen from *C. Sticklandii*, CA antigen from *C. aminophilum*, harvesting the eggs, spray drying and pasteurizing whole powdered egg, mixing said whole powdered egg in water supply, or a carrier such as pelleted soybean hulls and supplying said pelleted soybean hulls coated with the whole powdered egg containing the specific antibody to farm animal to inhibit the adherence of the specific immunogen in the intestinal tracts of the animal to promote the growth of the animals. The specification further discloses a method of reducing the incidence of food borne illness caused by the presence of common bacteria such as *E coli*, *Listeria*, *Salmonella* and *Campylobacter* by inhibiting the ability of said bacteria to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the bacteria to multiply, said method comprises inoculating female birds in or about to reach their egg laying age, with said bacteria, allowing a period of time sufficient to permit the production in the bird of the antibody to said bacteria,

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harvesting the eggs laid by the birds, separating the antibody-containing contents of the eggs from the shells, drying the separated antibody-containing contents of said eggs, distributing the resulting dried egg antibody uniformly through animal feed or water, supplying the resulting antibody-containing animal feed or water to food animals to prevent adherence of the targeted bacteria in the intestinal tract of the food animals

Other than the specific methods using the specific bacteria mentioned above, there is insufficient written description about the "colony-forming illness-causing immunogens" in the claimed methods.

Further, since the specification discloses only four bacteria that caused food borne illness in cattle herds such as *E coli*, *Listeria*, *Salmonella* and *Campylobacter* and three protein-wasting immunogens such as P antigen from *P anaerobius*, CS antigen from *C. Sticklandii*, CA antigen from *C. aminophilum*, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No. 5,080,895 (Jan 1992; PTO 1449).

The '895 patent teaches a method of reducing the incidence of illnesses such as diarrhea, colibacillosis by the presence of colony-forming illness-causing immunogen such as *E coli* in food animal or livestock such as piglets or calves (See entire document, abstract, column 5, lines 1-7, in particular). The reference method comprises the steps of inoculating an egg laying female birds such as hen against a selected immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks to permit the production of antibody in the bird of antibody to the targeted immunogen (See column 5, lines 57-66, in

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particular), harvesting the eggs laid by the birds (See column 6, line 1-8, in particular), separating the antibody-containing contents such as the yolk and albumen or the overall ovum from the shells (See column 6, lines 8-10, in particular), drying the separated antibody-containing contents of the eggs such as the yolk (See column 6, line 19-25, in particular), distributing the dried egg antibody product uniformly through an animal feed or food as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches that the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). Thus, the reference teachings anticipate the claimed invention.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
8. Claims 1, 3-4, 5-7 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of US Pat No 6,086,878 (July 2000, PTO 892), US Pat No 5,741,489 (April 1998, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The teachings of the '895 patent have been discussed supra.

The claimed invention in claims 3 and 6 differs from the teachings of the reference only that the method includes providing a dry feed carrier, coating the dry feed carrier with the separated antibody-containing contents of the eggs.

The claimed invention in claims 4, 7 and 18 differs from the teachings of the reference only that the method wherein the dry feed carrier material is selected from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The claimed invention in claim 17 differs from the teachings of the reference only that the method includes coating the dry feed carrier material with the antibody-containing contents of said eggs, distributing said carrier material coated with the antibody-containing contents of said eggs substantially uniformly in animal feed and supplying the resulting dry carrier material coated with the antibody containing contents of said eggs and animal feed to food animals to substantially prevent adherence of the immunogen in the rumen or intestinal tracts of the animals.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk from the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg (the entire content) as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular) and that egg antibodies are effective in decreasing the adhesion of enterotoxigenic *E coli* that causes food borne illness onto enterocytes and reduces the bacteria from multiply in livestock such as piglets and calves (See column 2, lines 49-61, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in

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particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to spray dry or to coat any dry feed carrier such as soybean hulls, rice hulls cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent with the separated antibody-containing contents of the eggs that binds to *E coli* as taught by the '895 patent for a method of reducing the incidence of illness caused by *E coli* by inhibiting the *E coli* from adhering to the rumen or intestinal tracts of livestock as taught by the '895 patent, the '867 patent and the '489 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-46). The '895 patent teaches the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective for a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (food animal), which inherently promotes the growth of livestock by decreasing diarrhea such as waste of dietary protein caused by the presence of protein-wasting immunogen (See abstract, and claims of '895, in particular). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg (the entire content) as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular) and that egg antibodies are effective in decreasing the adhesion of enterotoxigenic *E coli* that causes food borne illness onto enterocytes and reduces the bacteria from multiply in livestock such as piglets and calves (See column 2, lines 49-61, in particular).

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9. Claims 1, 2, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of Pell *et al* (J Dairy Sci 80: 2673-2681, 1997; PTO 892).

The teachings of the '895 patent have been discussed supra.

The claimed invention in claims 2 and 8 differs from the teachings of the reference only that the method wherein the colony-forming illness-causing immunogen is *Listeria*.

The claimed invention in claims 2 and 11 differs from the teachings of the reference only that the method wherein the colony-forming illness-causing immunogen is *Salmonella*.

Pell *et al* teach that pathogens (immunogens) such as *E Coli* O157:H7, *Listeria monocytogenes*, and *Salmonellas spp* are major problems for the swine and poultry industries and these microbes post potential threat to human health because many outbreaks have been traced to ground beef and some to raw milk in the case of *E Coli* (See page 2674, column 1, *E Coli* O157:H7, in particular). Pell *et al* further teach that more cow excreted *Listeria monocytogenes* during winter than summer and human infections have been associated with consumption of unpasteurized dairy products and healthy animals can be asymptomatic carriers (See page 2675, column 2, *L monocytogenes*). Pell *et al* also teaches that *Salmonella typhi* is the organism that responsible for 45% of the forborne disease in which the gastroenteritis have been traced to foods of animal origin and the economic costs of salmonellosis have been estimated at close to \$1 billion per year and that the problem has been exacerbated by increasing antimicrobial resistance among *Salmonella spp*. Serotypes (See page 2676, column 1, *Salmonella spp*, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the *E coli* immunogen as taught by the '895 patent for the immunogen such as *Listeria*, and *Salmonellas* as taught by Pell *et al* that post potential threat to human health because many outbreaks have been traced to meat in food animals where these immunogens adhere and multiply in the rumen or intestinal tracts of food animal such as piglets, calves and lambs. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Pell *et al* teach that pathogens (immunogens) such as *E Coli* O157:H7, *Listeria monocytogenes*, *Salmonellas spp* are major problems for the swine and poultry industries; the economic costs of salmonellosis have been estimated at close to \$1 billion per year and that the problem has been



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exacerbated by increasing antimicrobial resistance among *Salmonella spp.* Serotypes (See page 2676, column 1, *Salmonella spp.*, in particular). The '895 patent teaches that the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

10. Claims 3-4, 9-10, 12-13, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of Pell *et al* (J Dairy Sci 80: 2673-2681, 1997; PTO 892) as applied to claims 1, 2, 8, and 11 mentioned above and further in view of US Pat No 6,086,878 (July 2000, PTO 892), US Pat No 5,741,489 (April 1998, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The combined teachings of the '895 patent and Pell *et al* have been discussed supra.

The claimed invention in claims 3, 9, and 12 differs from the combined teachings of the references only that the method includes providing a dry feed carrier, coating the dry feed carrier with the separated antibody-containing contents of the eggs.

The claimed invention in claims 4, 10, 13 and 18 differs from the combined teachings of the references only that the method wherein the dry feed carrier material is selected from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The claimed invention in claim 17 differs from the combined teachings of the references only that the method includes coating the dry feed carrier material with the antibody-containing contents of said eggs, distributing said carrier material coated with the antibody-containing contents of said eggs substantially uniformly in animal feed and supplying the resulting dry carrier material coated with the antibody containing contents of said eggs and animal feed to food animals to substantially prevent adherence of the immunogen in the rumen or intestinal tracts of the animals.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

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The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg (the entire content) as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular) and that egg antibodies are effective in decreasing the adhesion of enterotoxigenic *E coli* that causes food borne illness onto enterocytes and reduces the bacteria from multiply in livestock such as piglets and calves (See column 2, lines 49-61, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to spray dry or to coat any dry feed carrier such as soybean hulls, rice hulls cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent with the separated antibody-containing contents of the eggs that binds to immunogen such as *Listeria monocytogenes*, and *Salmonellas spp* as taught by Pell *et al* for a method of reducing the incidence of illness by inhibiting the said immunogens from adhering to the rumen or intestinal tracts of livestock as taught by the '895 patent, the '867 patent and the '489 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-

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46). The '895 patent teaches the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective for a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (food animal), which inherently promotes the growth of livestock by decreasing diarrhea such as waste of dietary protein caused by the presence of protein-wasting immunogen (See abstract, and claims of '895, in particular). ). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg (the entire content) as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular) and that egg antibodies are effective in decreasing the adhesion of enterotoxigenic *E coli* that causes food borne illness onto enterocytes and reduces the bacteria from multiply in livestock such as piglets and calves (See column 2, lines 49-61, in particular). Pell *et al* teach that pathogens (immunogens) such as *E Coli* O157:H7, *Listeria monocytogenes*, *Salmonellas spp* are major problems for the swine and poultry industries; the economic costs of salmonellosis have been estimated at close to \$1 billion per year and that the problem has been exacerbated by increasing antimicrobial resistance among *Salmonella spp*. Serotypes (See page 2676, column 1, *Salmonella spp*, in particular). The '895 patent teaches that the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

11. Claims 1, 2, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of Adesiyun *et al* (Br Vet J 148(6): 547-56, 1992; PTO 892).

The teachings of the '895 patent have been discussed supra.

The claimed invention in claims 2 and 14 differs from the teachings of the reference only that the method wherein the colony-forming illness-causing immunogen is *Campylobacter*.

Adesiyun *et al* teach that *Campylobacter* bacteria causes diarrhea in animals. Piglets have the highest prevalence of campylobacters infection, follows by calves and lowest in lambs (See abstract, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the *E coli* immunogen as taught by the '895 patent for the

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immunogen such as the *Campylobacter* as taught by Adesiyun that pose potential threat to human health because many outbreaks have been traced to meat in food animals where these immunogens adhere and multiply in the rumen or intestinal tracts of food animal such as piglets, calves and lambs. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Adesiyun et al teach that *Campylobacter* bacteria causes diarrhea in food animals. Piglets have the highest prevalence of *campylobacters* infection, followed by calves and lowest in lambs (See abstract, in particular). The '895 patent teaches that the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

12. Claims 3-4, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of Adesiyun *et al* (Br Vet J 148(6): 547-56, 1992; PTO 892) as applied to claims 1, 2 and 14 mentioned above and further in view of US Pat No 6,086,878 (July 2000, PTO 892), US Pat No 5,741,489 (April 1998, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The combined teachings of the '895 patent and Adesiyun *et al* have been discussed supra.

The claimed invention in claim 3 differs from the combined teachings of the references only that the method includes providing a dry feed carrier, coating the dry feed carrier with the separated antibody-containing contents of the eggs.

The claimed invention in claims 4, 16 and 18 differs from the combined teachings of the references only that the method wherein the dry feed carrier material is selected from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The claimed invention in claim 17 differs from the combined teachings of the references only that the method includes coating the dry feed carrier material with the antibody-containing contents of said eggs, distributing said carrier material coated with the antibody-containing contents of said eggs substantially uniformly in animal feed and supplying the resulting dry carrier material coated with the antibody containing contents of said eggs and animal feed to food

animals to substantially prevent adherence of the immunogen in the rumen or intestinal tracts of the animals.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg (the entire content) as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular) and that egg antibodies are effective in decreasing the adhesion of enterotoxigenic *E coli* that causes food borne illness onto enterocytes and reduces the bacteria from multiply in livestock such as piglets and calves (See column 2, liens 49-61, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to spray dry or to coat any dry feed carrier such as soybean hulls, rice hulls cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent with the separated antibody-containing contents of the eggs that binds to immunogen such as *Campyloacter* as taught by Adesiyun *et al* for a method of reducing the incidence of illness by inhibiting the said immunogens from adhering to the rumen or intestinal tracts of livestock as

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taught by the '895 patent, the '867 patent and the '489 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-46). The '895 patent teaches the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective for a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (food animal), which inherently promotes the growth of livestock by decreasing diarrhea such as waste of dietary protein caused by the presence of protein-wasting immunogen (See abstract, and claims of '895, in particular). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg (the entire content) as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular) and that egg antibodies are effective in decreasing the adhesion of enterotoxigenic *E coli* that causes food borne illness onto enterocytes and reduces the bacteria from multiply in livestock such as piglets and calves (See column 2, lines 49-61, in particular). Adesiyun *et al* teach that *Campylobacter* bacteria causes diarrhea in animals. Piglets have the highest prevalence of *campylobacters* infection, follows by calves and lowest in lambs (See abstract, in particular). The '895 patent teaches that the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

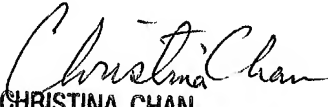
13. No claim is allowed.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner

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can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist (customer service) whose telephone number is (703) 872-9305.

15. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401. The IFW official Fax number is (703) 872-9306. For After Final, the Fax number is (703) 872-9307.

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